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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 3

[Docket No. APHIS-2014-0098]

Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service has received a petition requesting that we amend the Animal Welfare Act regulations to specify ethologically appropriate standards that researchers must adhere to in order to promote the psychological well-being of nonhuman primates used in research. We are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition.

DATES: We will consider all comments that we receive on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0098>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0098, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0098> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Carol Clarke, Research Program Manager, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737-1234; (301) 851-3751.

SUPPLEMENTARY INFORMATION: The Animal Welfare Act (AWA, 7 U.S.C. 2131 et seq.), among other things, authorizes the Secretary of Agriculture (Secretary) to promulgate standards and other requirements governing research facilities. The Secretary has delegated the responsibility for enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care.

Regulations and standards promulgated under the AWA are contained in Title 9 of the Code of Federal Regulations, parts 1, 2, and 3 (referred to collectively below as the AWA regulations). Part 3 of the AWA regulations contains specific standards regarding the humane handling, care, treatment, and transportation of species of animals covered under the AWA.

Within part 3 of the AWA regulations, subpart D (§§ 3.75-3.92) contains standards for the humane handling, care, treatment, and transportation of nonhuman primates.

Section 3.81 of the AWA regulations requires research facilities that house nonhuman primates to develop, document, and follow an appropriate plan for environmental enhancement adequate to promote the psychological well-being of nonhuman primates. The section further specifies that the plan must be in accordance with currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian for the facility. The plan must be available to APHIS upon request, and in the case of research facilities, it must also be available to the funding agency. The plan must address at a minimum: Social grouping, environmental enrichment, special considerations, and use of restraint devices. Exemptions to the plan can be made by the attending veterinarian for the facility because of a particular animal's health or condition, or in consideration of that animal's well-being. Additionally, the Institutional Animal Care and Use Committee (IACUC), a committee entrusted with ensuring the research facility's compliance with the AWA regulations, may exempt individual nonhuman primates from the plan for scientific reasons, provided these reasons are set forth in a research proposal and reviewed by the IACUC.

On May 7, 2014, APHIS received a petition submitted jointly by the New England Anti-Vivisection Society, the North American Primate Sanctuary Alliance, the Laboratory Primate Advocacy Group, and the Animal Legal Defense Fund requesting that we initiate rulemaking to amend the AWA regulations. Specifically, the petition asks that we amend § 3.81 to require that research facilities construct and maintain an ethologically appropriate environment for nonhuman primates housed at the facilities, that is, an environment that is appropriate with respect to the patterns of behavior exhibited by the nonhuman primates in their natural state. The

petition also asks that we amend § 3.81 to specify minimum standards that must be met in order for an environment to be considered ethologically appropriate. The petition cites standards recently adopted by the National Institutes of Health (NIH) for chimpanzees used in NIH-funded research as a reference point for the development of such generally applicable minimum standards and as evidence of their feasibility.

The petition agrees that the intent of § 3.81 of the AWA regulations is to ensure that the environment provided to nonhuman primates housed at research facilities promotes the psychological well-being of the primates. The petition suggests, however, that because of ambiguities in the current regulations, research facilities have broad discretion regarding the actual environment provided to nonhuman primates at their facilities, and can meet the requirements in § 3.81 without actually meeting their intent.

The petition states that, by amending the AWA regulations in the manner that the petitioners suggest, we would remove these ambiguities and facilitate regulatory compliance.

We are making this petition available to the public and soliciting comments to help determine what action, if any, to take in response to this request. The petition and any comments submitted are available for review as indicated under ADDRESSES above. We welcome all comments on the issues outlined in the petition. In particular, we invite responses to the following questions:

1. Should APHIS amend § 3.81 of the AWA regulations to require research facilities to construct and maintain an ethologically appropriate environment for nonhuman primates, and specify the minimum standards that must be met for an environment to be considered ethologically appropriate?

2. What constitutes an ethologically appropriate environment for a nonhuman primate?

Does this differ among species of nonhuman primates? If so, how does it differ?

3. Are there any environmental conditions that make an environment ethologically inappropriate for a nonhuman primate? If so, what are they? Do they differ among species of nonhuman primates?

4. Does an ethologically appropriate environment for nonhuman primates used in research differ from an ethologically appropriate environment for nonhuman primates that are sold or exhibited? If so, in what ways does it differ?

5. Who should make the determination regarding the ethological appropriateness of the environment for nonhuman primates at a particular research facility: The attending veterinarian for the facility, APHIS, or both parties? If both parties should jointly make such a determination, which responsibilities should fall to the attending veterinarian and which to APHIS?

We encourage the submission of scientific data, studies, or research to support your comments and position. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments and recommendations received.

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 27th day of April 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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